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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/498,556	02/04/2000	George Phillip Vlasuk	250/191	8959

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PILLSBURY WINTHROP LLP
INTELLECTUAL PROPERTY GROUP
11682 ELCAMINO REAL
SUITE 200
SAN DIEGO, CA 92130

EXAMINER

MITRA, RITA

ART UNIT PAPER NUMBER

1653

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/498,556	Applicant(s) VLASUK ET AL.	
	Examiner Rita Mitra	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 270-282 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 270-282 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

Applicants' amendment and response to office action dated May 6, 2003 filed on September 8, 2003, is acknowledged. Claims 1-269 have been cancelled. Claims 270-274 have been amended. Therefore, claims 270-282 are currently pending and are under examination.

Response to Remarks and Arguments

The rejection of claims 270, 271 and 272 and dependent claims thereto under **35 U.S.C. § 112, second paragraph** is withdrawn in view of Applicants' amendment to the claims.

The rejection of claims 270-274 under **35 U.S.C. § 112, second paragraph** is withdrawn in view of Applicants' amendment to the claims.

The rejection of claims 270 and 271 under **35 U.S.C. § 112, second paragraph** is withdrawn in view of Applicants' amendment to the claims.

The rejection of claims 275-281 under **35 U.S.C. § 112, second paragraph** is withdrawn in view of Applicants' amendment to the claims.

The rejection of claims 270, 271, 275 and 282 under **Nonstatutory Double Patenting** is withdrawn in view of Applicants' filing the terminal disclaimer in compliance with 37 CFR 1.32(c).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 270-282 stand/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 270 (e, j), 271 (h, j), 272 and 273 reciting "SEQ. ID. NO.", "SEQ ID NO:" should be used. Claims 275-278 and 280-282 are included in the rejection because these claims are dependent on rejected claim and do not correct the deficiency of the claim from which they depend.

Claims 270-274, and dependent claims thereto are indefinite because of the use of the term "AcaNAPc2." The term "AcaNAPc2" renders the claim indefinite, it is unclear what "AcaNAPc2" is. The full spelled out words should precede an acronym/abbreviation. Claims 275-282 are included in the rejection because these claims are dependent on rejected claim and do not correct the deficiency of the claim from which they depend.

Claims 270, 271, 272 and 273 are indefinite because the claims include extra number of periods ("."). It is not clear where the claim ends. See MPEP 608.01 (m) (each claim begins with a capital letter and ends with a period). Claims 275-278 and 280-282 are included in the rejection because these claims are dependent on rejected claim and do not correct the deficiency of the claim from which they depend.

Claim Rejections - Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van*

Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 270 and 271 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9, 10, 22, 23, 31, 32 of U.S. Patent No. 5,864,009. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 270 and 271 are directed to the broadest scope of the protein having anticoagulant activity and having one or more NAP domains. Claims 270 and 271 encompass the amino acid sequences set forth in claims 9, 10, 22, 23, 31 and 32 of patent '009.

Claim 270 (a) discloses an amino acid sequence A1 having an amino acid sequence of 7 to 8 amino acid residues. This is an obvious variation of claims 10(a), 23(a) and 32(a), and the independent claims (9, 22, 31) they depend upon, in the patent '009, which discloses an amino acid sequence A1 containing 7 to 8 amino acid residues.

Claim 270 (b) discloses an amino acid sequence A2 having any amino acid residues. This is an obvious variation of claims 10(b), 23(b), 32(b), and the independent claims (9, 22, 31) they depend upon, in the patent '009, which discloses an amino acid sequence A2 containing 2-5 amino acid residues.

Claim 270 (c) discloses an amino acid sequence A3 having 3 amino acid residues and has the sequence Asp-A3a-A3b, wherein A3a and A3b are independently selected. This is an obvious variation of claims 10(c), 23(c), 32(c), and the independent claims (9, 22, 31) they depend upon, in the patent '009, which discloses an amino acid sequence A3 containing any 3 amino acid residues.

Claim 270 (d) discloses an amino acid sequence A4 having a net anionic charge. This is an obvious variation of claims 10(d), 23(d), 32(d), and the independent claims (9, 22, 31) they depend upon, in the patent '009, which discloses an amino acid sequence A4 having any charge.

Claim 270 (e) discloses an amino acid sequence A5 having 4 amino acid residues A5a-A5b-A5c-A5d (SEQ ID NO: 85). This is an obvious variation of claims 10(e), 23(e), 32(e), and the independent claims (9, 22, 31) they depend upon, in the patent '009, which discloses an amino acid sequence A5 having 3-4 amino acid residues.

Claim 270 (f) discloses an amino acid sequence A6. This is an obvious variation of claims 10(f), 23(f), 32(f), and the independent claims (9, 22, 31) they depend upon, in the patent '009, which discloses an amino acid sequence A6 having 3-5 amino acid residues.

Claim 270 (g) discloses an amino acid sequence A7, residues selected from the group consisting of val and Ile. This is an obvious variation of claims 10(g), 23(g), 32(g), and the independent claims (9, 22, 31) they depend upon, in the patent '009, which discloses an amino acid sequence A7 having any amino acid residues.

Claim 270 (h) discloses an amino acid sequence A8 having 11-12 amino acid residues. This is an obvious variation of claims 10(h), 23(h), 32(h), and the independent claims (9, 22, 31) they depend upon, in the patent '009, which discloses an amino acid sequence A8 having 10-12 amino acid residues.

Claim 270 (j) discloses an amino acid sequence A9 having 5-7 amino acid residues. This is an obvious variation of claims 10(j), 23(i), 32(i), and the independent claims (9, 22, 31) they depend upon, in the patent '009, which discloses an amino acid sequence A9 having 5-6 amino acid residues.

Claim 271 (a) discloses an amino acid sequence A1 having an amino acid sequence of 7 to 8 amino acid residues. This is an obvious variation of claims 10(a), 23(a) and 32(a), and the independent claims (9, 22, 31) they depend upon, in the patent '009, which discloses an amino acid sequence A1 containing 7 to 8 amino acid residues.

Claim 271 (b) discloses an amino acid sequence A2 having any amino acid residues. This is an obvious variation of claims 10(b), 23(b), 32(b), and the independent claims (9, 22, 31) they depend upon, in the patent '009, which discloses an amino acid sequence A2 containing 2-5 amino acid residues.

Claim 271 (c) discloses an amino acid sequence A3 having 3 amino acid residue and has the sequence Asp-Lys-Lys. This is an obvious variation of claims 10(c), 23(c), 32(c), and the

independent claims (9, 22, 31) they depend upon, in the patent '009, which discloses an amino acid sequence A3 containing any 3 amino acid residues.

Claim 271 (d) discloses an amino acid sequence A4 having a net anionic charge. This is an obvious variation of claims 10(d), 23(d), 32(d), and the independent claims (9, 22, 31) they depend upon, in the patent '009, which discloses an amino acid sequence A4 having any charge.

Claim 271 (e) discloses an amino acid sequence A5 having 4 amino acid residues A5a-A5b-A5c-A5d, wherein A5a is Leu, A5c is Arg and A5b and A5d are independently selected amino acid residues (SEQ ID NO: 357). This is an obvious variation of claims 10(e), 23(e), 32(e), and the independent claims (9, 22, 31) they depend upon, in the patent '009, which discloses an amino acid sequence A5 having 3-4 amino acid residues.

Claim 271 (f) discloses an amino acid sequence A6. This is an obvious variation of claims 10(f), 23(f), 32(f), and the independent claims (9, 22, 31) they depend upon, in the patent '009, which discloses an amino acid sequence A6 having 3-5 amino acid residues.

Claim 271 (g) discloses an amino acid sequence A7, which is val. This is an obvious variation of claims 10(g), 23(g), 32(g), and the independent claims (9, 22, 31) they depend upon, in the patent '009, which discloses A7 is an amino acid residue.

Claim 271 (h) discloses an amino acid sequence A8 having 11-12 amino acid residues and includes the amino acid sequence A8a-A8b-Gly-Phe-Tyr-Arg-Asn (SEQ ID NO: 79), wherein at least one of A8a and A8b is Glu or Asp. This is an obvious variation of claims 10(h), 23(h), 32(h), and the independent claims (9, 22, 31) they depend upon, in the patent '009, which discloses an amino acid sequence A8 having 10-12 amino acid residues.

Claim 271 (j) discloses an amino acid sequence A9 having 5-7 amino acid residues. This is an obvious variation of claims 10(j), 23(i), 32(i), and the independent claims (9, 22, 31) they depend upon, in the patent '009, which discloses an amino acid sequence A9 having 5-6 amino acid residues.

Thus, claims 270 and 271 in present application and claims 9, 10, 22, 23, 31 and 32 in the patent '009 are obvious variations of an isolated protein having an anticoagulant activity and NAP domains, wherein each NAP domain includes the sequence:

Cys-A1-Cys-A2-Cys-A3-Cys-A4- Cys-A5-Cys-A6- Cys-A7-Cys-A8-Cys-A9-Cys-A10
(formula III).

Conclusion

No claims are allowable.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rita Mitra, Ph.D.

December 24, 2003



ROBERT A. WAY
PRIMARY EXAMINER